



K962974

510(k) Summary of Safety and Effectiveness
Sharplan Lasers, Inc. Model 713 AF Acuspot Micromanipulator

AUG 21 1996

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the Sharplan Model 713 AF Acuspot Micromanipulator is based on a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices which include the Sharplan Model 712 Acuspot, the Reliant UniMax Model 2000 Micromanipulator, and the Heraeus LaserSonics Ultraspot Micromanipulator.

1. Sharplan Lasers, Inc.
1 Pearl Court
Allendale, NJ 07401
George J. Hattub, Director of Regulatory Affairs/Quality Assurance
July 8, 1996
2. **Model:** Sharplan Model 713 AF Acuspot Micromanipulator
3. **Predicate Devices:** The Sharplan Model 712 Acuspot Micromanipulator, the Reliant UniMax Model 2000 Micromanipulator, and the Heraeus LaserSonics Ultraspot Micromanipulator.
4. **Description:** The Sharplan Model 713 AF Acuspot Micromanipulator is an accessory for a CO2 Surgical Laser. It attaches to the distal end of an articulated arm and connects to a surgical microscope. Its purpose is to allow a physician the ability to focus and steer laser beams so that when tissue is visualized, it can be selectively treated.
5. The Sharplan Model 713 AF Acuspot Micromanipulator is substantially equivalent to the following devices: The Sharplan Model 712 Micromanipulator, the Reliant UniMax Model 2000, and the Heraeus LaserSonics Ultraspot Micromanipulator. It is indicated for incision, excision, coagulation, ablation, and vaporization of soft tissue, to be used with compatible, legally marketed surgical lasers.

No new indications were sought in the premarket notification and no clinical data was presented.

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Sharplan Lasers, Inc. Model 712 Acuspot Micromanipulator

6. From a design and intended use perspective, the aforementioned devices, while are not identical, perform the same function and are of the same technology. The modification to the candidate device, involves the addition of an autofocus option. Based upon an analysis of the overall performance characteristics for the devices, Sharplan Lasers, Inc. believes that no significant differences exist. Furthermore, this modification raises no concerns regarding the safety or effectiveness of the Sharplan Model 713 AF Acusot Micromanipulator.

Advisory: This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients due to operator error or in procedures requiring a high degree of skill.